DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 2, 2002

WARNING LETTER NYK 2003-07

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Scott Blond, DVM
366 Crossman Road
Wyoming, NY 14591

Dear Dr. Blond:

An illegal residue investigation performed by U.S. Food and Drug Administration Investigators William P. Chilton and Harry J. Brewer included a visit to your veterinary practice on August 28 and September 5, 2002. The investigation revealed that drug products you administered at [redacted] were responsible for illegal tissue residues in two cows subsequently offered for slaughter for human food.

These include flunixin residues, one found in the liver tissue of a cow slaughtered on March 1, 2002, and another found in the liver tissue of a second cow slaughtered on April 30, 2002. Both cows were slaughtered at [redacted] The presence of these drugs, at the reported levels of 1.38 ppm and 0.18 ppm, respectively, in edible tissues of these animals, causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). The fact that extra label usage of flunixin resulted in residues which may present a risk to public health and which are above an established tolerance causes the drug to be adulterated under Section 501(a)(5) of the Act.

The flunixin residue in the first cow resulted from the extra label use at [redacted] of Banamine (flunixin meglumine) Injectable Solution. The investigation revealed that on February 26, 2002, you administered 10 ml of this drug along with two 15 gram boluses of Albon (sulfadimethoxine) to a lactating cow at [redacted] for the treatment of pneumonia. Banamine is not approved for the treatment of lactating and dry dairy cows; therefore its use in the treatment of this lactating cow is considered extra label usage. The identity of the cow was not maintained and no follow-up examination was performed. You failed to institute procedures to maintain the identity of the treated cow, establish a substantially extended withdrawal period for beef supported by appropriate scientific information and take appropriate measures to assure that assigned withdrawal times were satisfied.

The flunixin residue in the second cow resulted from the extra label use at [redacted] of Banamine (flunixin meglumine) Injectable Solution. The investigation revealed that on April 19, 2002, you administered Liquamycin LA-200 (oxytetracycline injection) and Banamine (flunixin meglumine) Injectable Solution to a lactating cow at [redacted] for the treatment of pneumonia. Banamine is not approved for the treatment of lactating and dry dairy cows; therefore its use in the treatment of this lactating cow is considered extra label usage. The identity of the cow was not maintained and no follow-up examination was performed. You failed to institute procedures to maintain the identify of the treated cow, establish a substantially extended withdrawal period for beef supported by appropriate scientific information and take appropriate measures to assure that assigned withdrawal times were satisfied.

The flunixin meglumine you administered is adulterated under Section 501(a)(5) and within the meaning of Section 512 of the Act. Section 512 deems, in part, a new animal drug is unsafe unless an FDA approved application is in effect and the drug, its labeling and use conform to such approved application or the implementing regulations for "Extralabel Drug Use in Animals", 21 Code of Federal Regulations (CFR) Part 530. The extra label use of approved veterinary or human drug by veterinarians is allowed under the Animal Medicinal Drug Use Clarification Act (AMDUCA), provided that the regulations contained in 21 CFR Part 530 are followed.

21 CFR 530.5 imposes recordkeeping requirements for veterinarians prescribing drugs for extra label usage. Our investigation revealed you are not complying with this regulation in that you did not maintain extra label treatment records for these two cows.

21 CFR 530.20(a)(2) discusses what the veterinarian is required to do prior to prescribing or dispensing an approved new animal drug for an extra label use. Specifically, the veterinarian must establish a substantially extended withdrawal period prior to marketing of meat products supported by appropriate scientific information, if applicable [21 CFR 530.20(a)(2)(ii)]; institute procedures to assure that the identity of the treated animal or animals is carefully maintained [21 CFR 530.20(a)(2)(iii); and take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animals subjected to extra label treatment [21 CFR 530.20(a)(2)(iv)]. The fact that a residue occurred from your extra label treatment indicates you did not comply with these parts of 21 CFR 530.20(a)(2).

The above is not intended to be an all-inclusive list of violations. When you administer and/or dispense an animal drug for extra label use in the treatment of disease conditions in food producing animals, you assume added responsibility. You must establish a substantially extended withholding period supported by appropriate scientific information, you must assure the identity of a treated animal and that treatment records are carefully maintained, and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and that no illegal residues occur. This includes assuring that your clients will follow your instructions.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that the extra label drug usage administered by you resulted in the adulteration of animals that were subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action - without further notice. This may include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Buffalo, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

Jerome G. Woyshner/pac

Jerome G. Woyshner
District Director